



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ICD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/468,161 06/06/95 DEFEO-JONES D 192531B

HM12/0806

DAVID A MUTHARD
PATENT DEPARTMENT
MERCK & CO INC
PO BOX 2000
RAHWAY NJ 07065-0907

EXAMINER

DELACROIX MUIRHEI, C

ART UNIT

PAPER NUMBER

1654

DATE MAILED:

08/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/468,161

Applicant(s)

DeFeo-Jones et al

Examiner

C. Delacroix-m

Group Art Unit

1654

☒ Responsive to communication(s) filed on 7/27/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21, 13-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 21, 13-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Continued Prosecution Application

1. The request filed on July 27, 1998 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/468,161 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 21 and 13-19 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statement received July 27, 1998 has been considered in part. The US patents, which are readily available to the Examiner, have been considered. However, the remaining references were not submitted by Applicant and there is no indication by Applicant that the remaining references were submitted in a parent application. Applicant is respectfully requested to submit the remaining references for consideration.

Claim Rejections - 35 USC § 112

2. Claim 21 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/ or use the invention. The present invention is drawn to conjugates comprising a cytotoxic agent attached to an oligopeptide that is recognized and selectively proteolytically cleaved by prostate specific antigen (PSA), wherein said conjugates are to be used in vivo for the treatment of prostate cancer. However, the specification, while being enabling for making the claimed conjugates, does not enable one of ordinary skill in the art to successfully use the conjugates. It is known that PSA, which is used as a marker for prostate cancer, is readily available in the blood and is present in the blood at higher concentrations in individuals suffering from

prostate cancer. Therefore, it is not clear how the cytotoxic agent/oligopeptide conjugate localizes in the tissue to be treated without being cleaved by the higher levels of PSA in the blood. Applicant's specification does not provide any explanation on how the claimed conjugates would be readily available to treat prostate cancer.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 21, 13-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,866,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and patent '679 disclose conjugates comprising cytotoxic agents, i.e. doxorubicin and vinblastine, attached to an oligopeptide that is recognized and selectively proteolytically cleaved by prostate specific antigen (PSA), wherein the means of attachment is a covalent bond or chemical linker, and the oligopeptide does not comprise semenogelin I or semenogelin II. Both the instant application and patent '679 claim the use of said conjugates in vivo for treating prostate cancer. The scope of the claims of the instant application and that of patent '679 overlaps because the claims of the instant application claim conjugates comprising a cytotoxic agent attached to an oligopeptide, (wherein the oligopeptides of the instant invention and that of '679 overlap), whereas the claims of '679, in addition to reciting a cytotoxic agent conjugated to an oligopeptide that is cleaved by PSA, also recite conjugates wherein two cytotoxic agents are attached to an oligopeptide cleaved by PSA.

Application/Control Number: 08/468,161

Page 4

Art Unit: 1654

Applicant: DEFEO-JONES et al.

Conclusion

Claims 21 and 13-19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward PhD, can be reached on (703) 308-4028. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM



Aug. 1, 1999



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600